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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,522	12/09/2003	Sudhir V. Shah	2629.1003-009	3719

21005 7590 05/05/2004

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EXAMINER

WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/731,522	SHAH, SUDHIR V.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Randall Winston	1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for a method for diagnosing a kidney disease in a human comprising the step of measuring catalytic iron in a urine sample from the human, wherein the urine sample is obtained from a human having kidney disease selected from the group consisting of diabetic nephropathy, primary glomerulonephritis and secondary glomerulonephritis the specification does not enable any person in the art for preparing a method for diagnosing any and/or all kidney disease in a human comprising the step of measuring catalytic iron in a urine sample from the human.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a method for diagnosing any and/or all kidney disease in a human comprising the step of measuring catalytic iron in a urine sample from the

human. Applicant has reasonably demonstrated on pages 35-40 and especially page 35 lines 14-19 of the specification a method for diagnosing a kidney disease in a human comprising the step of measuring catalytic iron in a urine sample from the human, wherein the urine sample is obtained from a human having kidney disease selected from the group consisting of diabetic nephropathy, primary glomerulonephritis and secondary glomerulonephritis. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method for diagnosing any and/or all kidney disease in a human comprising the step of measuring catalytic iron in a urine sample from the human.

Moreover, it should be noted that the state of the prior art at the time the invention was filed did not recognize a method for diagnosing any and/or all kidney disease in a human comprising the step of measuring catalytic iron in a urine sample from the human. For example, Suzuki teaches (US 5,047,329, see, e.g., column 1 lines 12-15 and column 2 lines 55-57) a measurement of creatine or creatinine in urine of humans to test for kidney disease. Thus, the art is silent regarding the efficacy of applicant's method for diagnosing any and/or all kidney disease in a human comprising the step of measuring catalytic iron in a urine sample from the human. Therefore, applicant's claimed method is unpredictable in the art.

Furthermore, applicant's specification has reasonably demonstrated on pages 35-40 and especially page 35 lines 14-19 of the specification a method for diagnosing a kidney disease in a human comprising the step of measuring catalytic iron in a urine sample from the human, wherein the urine sample is obtained from a human having

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kidney disease selected from the group consisting of diabetic nephropathy, primary glomerulonephritis and secondary glomerulonephritis. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method for diagnosing any and/or all kidney disease in a human comprising the step of measuring catalytic iron in a urine sample from the human. Therefore, it would require undue experimentation by one of skill in the art to practice the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "a progressive kidney disease." There is insufficient antecedent basis for this limitation in the claim. Further, the metes and bounds of progressive kidney disease have not been delineated.

All other claims depend directly or indirectly from the rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth.

Please Note claims 1-4 are free of the art because there is no motivation in the prior art to prepare a method for diagnosing a kidney disease in a human comprising the step of measuring catalytic iron in a urine sample from the human, wherein the urine

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sample is obtained from a human having kidney disease selected from the group consisting of diabetic nephropathy, primary glomerulonephritis and secondary glomerulonephritis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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*Brenda Brumback*  
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